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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,664	DE LEYS ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31 and 37-41* is/are pending in the application.

4a) Of the above claim(s) *38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,37 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies no

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Sum Paper No(s)/Ma
5) ☐ Notice of Inform
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 7-23-2004 are acknowledged. Claims 31 and 41 have been amended. Claims 38-40 remain withdrawn from consideration. Claims 31, 37 and 41 are currently under examination.

Objections Withdrawn

The objection to the specification for failing to reflect the current status of each prior application to which priority has been claimed is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 31 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the recitation of the phrase "...at least 360 contiguous sequences corresponding to the genomic RNA of the HIV-3..." is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The new matter rejection of claims 31, 37 and 41 are rejected under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

As outlined previously claim 41 to recites "... wherein the DNA probe **specifically hybridizes** with the genomic RNA of the HIV-3 retrovirus...". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. No particular amino acid sequence of any probe that specifically hybridizes to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Therefore this limitation is new matter.

Applicant argues:

1. The term "specific" with respect to nucleic acid probes is explicitly disclosed on page 2 of the specification.

2. The term "specifically hybridizes" was well known and widely used by those of skill in the art at the time the application was filed as illustrated by the cited references.

3. The specification provides implicit support for the use of said term. At page 2 the specification describes specific probes as "hybridizing preferentially" to the target DNA.

4. Figure 14 illustrates that under "stringent conditions" there is no cross-hybridization between HIV-1, HIV-2 and HIV-3 (i.e. the hybridization are specific).

5. Stringent and non-stringent are described at pages 17 and 37 respectively.

6. Addition of the phrase "under stringent conditions" immediately subsequent to the term "specifically hybridizes" renders the term's meaning clear to one of skill in the art.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the recitation of "probes specific to HIV-2" does not provide implicit support for the term "specifically hybridizes" since said probes also hybridize to SIVagm sequences.

With regard to Point 2, the term "specifically hybridizes" (contrary to Applicant's assertion) is not well known in the art. Moreover, the cited references do not define said term.

With regard to Point 3, the description of specific probes as "hybridizing preferentially" to the target DNA (page 2 of Specification) does not provide implicit support for the term "specifically hybridizes" since "specifically" and "preferentially" are not synonymous terms.

With regard to Point 4, while Figure 14 demonstrates that there is no cross-hybridization between HIV-3 (ANT 70), HIV-1 (SF-4) and HIV-2 (53) probes under specific conditions (not defined in figure or in description of drawing), it does not provide implicit support for the term "specifically hybridizes". Cross-reactivity is a governed by the hybridization conditions. Since "stringent conditions" are not explicitly defined in the specification, Figure 14 does not provide support for the term "specifically hybridizes" as it applies to all HIV-3 probes.

With regard to Point 5, the conditions associated with the term "stringent conditions" are not explicitly set forth in the specification. The portions of the specification cited by Applicant, recite differing parameters for what is considered to be "stringent conditions".

With regard to Point 6, addition of the phrase "under stringent conditions" immediately subsequent to the term "specifically hybridizes" does not render the term's meaning clear since there the conditions associated with the term "stringent conditions" are not explicitly set forth in the specification.

Therefore, for the reasons set forth above, the rejection is deemed to be proper and hence is maintained.

Written Description Rejection

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The rejection of claims 31and 41 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record.

Applicant argues:

1. In view of Enzo, the deposited material of the instant claims provides the written description required by 35 U.S.C. 112, first paragraph.

2. The presently rejected claims refer to nucleic acids that are publicly available via a biological deposit.

3. The fact that the retrovirus was deposited would convince one of ordinary skill in the art that the inventors were in possession of the invention at the time the application was filed.

4. SEQ ID NO:1 corresponds to an HIV-3 LTR from clone iso 70-11. Clone iso 70-11 was isolated from the ANT70 strain that was deposited as ECACC V88060301. Hence SEQ ID NO:1 clearly falls within the limitations of claims 31 and 41.

Applicant's arguments have been fully considered and deemed non-persuasive.

Contrary to Applicant's assertions (Points 1-3), Enzo is germane. Carefully reading of the Enzo decision shows that a biological deposit satisfies the written description requirement for the nucleic acids of the deposited material. The instant claims are drawn to probes that hybridize to the genomic RNA of a deposited retrovirus under undefined conditions. Hence, the specification provides insufficient written description to support the genus encompassed by the claim.

With regard to Point 4, as stated in the rejection, the specification discloses SEQ ID NO:1 that corresponds to a portion of the HIV-3 cDNA (iso 70-11 clone). SEQ ID NO:1 meets the written description provision of 35 USC 112, first paragraph (which is why claim 37 was not included in the rejection). However, the aforementioned claims are directed to encompass the vast genus of probes that specifically hybridize to genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. This vast genus fails to meet the written description provision of 35 USC 112, first paragraph.

Enablement Rejection

The rejection of claims 31, 37 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. The term "specifically hybridizes" is implicitly defined in the specification (see above).

2. The term "stringent conditions " is clearly defined in the specification (see above).

3. The specification unambiguously teaches how to make DNA probes encompassed by the claims as illustrated with the preparation of SEQ ID NO:1.

4. The claimed probes are intended to detect the presence of intact HIV-3 retrovirus so there is no need to limit the probe to a particular reading frame, exon or protein since said probes are meant to detect the RNA from whole virus that , by definition, comprise the entirety of the HIV-3 genome.

5. The specification clearly provides sufficient guidance allowing those of skill in the art to prepare probes from the biological deposit without any undue experimentation.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, neither the term "specifically hybridizes" nor the term "stringent conditions" have been explicitly (or implicitly) defined in the specification (see above).

With regard to Points 2 and 5, the probes of claimed invention are not limited to those derived **from** the deposited material. They encompass all probes that hybridize **to** the genomic RNA of the deposited material.

With regard to Point 4, the instant claims are not limited to the detection of intact virus as they are drawn to "a process for the detection of HIV-3 retrovirus **or of its RNA**".

As outlined in the previous Office action, claims 31 and 41 encompass polynucleotides (DNA probes) comprising non-disclosed nucleic acid sequences that **specifically hybridize** to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301 under stringent conditions. Claim 37 is drawn to DNA

probes comprising SEQ ID NO:1 or the complement of SEQ ID NO:1. The specification teaches that "stringent conditions" refer to "the conditions under which the actual hybridization and/or the subsequent wash steps are performed" (see page 16, line36 to page 17, line 2). The specification fails to specifically define what parameters constitute "stringent conditions". Therefore, said term is not limiting. As disclosed above, the specification does not teach how to make any polynucleotides that specifically hybridizes to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Clearly, since the specification has not taught how to make/use said polynucleotides, the specification has not enabled the instant claims that require DNA probes that specifically hybridize to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Said probes include those comprising SEQ ID NO:1 or the complement of thereof. When given the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes and protein coding regions. Moreover, the use of the term "comprising" (claim 37) and "contains" (claim 31) reads on intact genomic material comprising enhancers, promoters, introns, and splice sites, etc. No open reading frames are identified in any sequence such that one of skill in the art would be able to determine where such features could be within the sequence. Clearly, it would be expected that a substantial number of the hybridizing or complementary polynucleotides encompassed by the claims would not share either structural or functional properties with polynucleotides that encode SEQ ID NO:1 or its complement. The specification fails to provide an enabling disclosure for how one would make such polynucleotides. The specification provides insufficient guidance with regard to these issues

and provides no working examples that would provide guidance to one skilled in the art on how to make/use the broadly claimed genus. For the above reasons, undue experimentation would be required to practice the claimed invention. Hence, the rejection is deemed proper and is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 37 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "stringent hybridization conditions" is maintained for reasons of record. It is still unclear what parameters are encompassed by said phrase as the specification fails to provide a definition. Applicant's arguments have been addressed above.

The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "specifically hybridizes" is maintained for reasons of record. It is still unclear what is meant by said term. Applicant's arguments have been addressed above.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 31 and 41 under 35 U.S.C. 102(b) as being anticipated by Montagnier et al. (WO 86/02383 – IDS- 5/9/2001) is maintained for reasons of record.

Applicant argues:

1. The amended claims are limited to processes that require probes that specifically hybridize under stringent conditions with the deposited HIV-3 RNA.

2. As illustrated in Figure 14, probes for HIV-1 or HIV-2 do not recognize HIV-3 under "stringent conditions".

3. Montagnier et al. can't anticipate the present claims because they do not teach or describe probes capable of "specifically hybridizing [to HIV-3] under stringent conditions".

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 3, the terms "specifically hybridizes" and "stringent conditions" have not been explicitly defined in the specification (see above). Therefore, said terms are not limiting.

With regard to Point 2, while Figure 14 demonstrates that there is no cross-hybridization between HIV-3 (ANT 70), HIV-1 (SF-4) and HIV-2 (53) probes under "stringent conditions" (not defined in figure or in description of drawing), it does not provide implicit support for the term "specifically hybridizes". Cross-reactivity is a governed by the hybridization conditions. Since "stringent conditions" are not explicitly defined in the specification, Figure 14 does not provide support for the term "specifically hybridizes" as it applies to all HIV-3 probes.

Consequently, since Montagnier et al. disclose methods for the use of DNA hybridization probes for the detection of LAV (HIV) in tissues and fluids (see page 38-39) it is deemed, in the absence of evidence to the contrary, that one of the probes encompassed by the Montagnier et al. disclosure will be effective in the detection of HIV-3 or its RNA since the hybridization conditions and the limitation "specifically" have not been defined.

Conclusion

No claim is allowed.

SEQ ID NO:1 is free of the art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
October 28, 2004

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